AMENDMENTS TO THE SPECIFICATION:

Please delete paragraphs [0055] and [0084].

Please add after paragraph [0004] the following two paragraphs, the contents of which were taken from former paragraphs [0055] and [0084].

A harness is constructed of polyester filaments knit in a well known "Atlas knit" arrangement, such as that discussed in international patent Publication Number WO 01/95830 A2, which is incorporated herein by reference in its entirety. As such, the harness is flexible, and the fabric can stretch, even though the polyester filaments do not necessarily elastically deform upon stretching of the fabric. Such fabric stretch is mainly due to linearization of filaments and fiber crimp and geometric distortion of the knit pattern. Once these stretch factors are exhausted, the harness becomes inelastic, and will no longer expand elastically with an increase in size of a patient's heart.

With reference to Figure 13, an anticipated compliance curve charting the compliance of a cardiac harness constructed of a knit material such as a harness constructed employing an "atlas knit" as discussed above. As shown in the drawing, the curve appears generally parabolic in shape. That is, as the percent tensile strain increases the corresponding load increases exponentially. It is anticipated that an asymptote will be defined at a percent strain between about 40%-50%. At that point the limit of expansion will have been reached.

Please amend the following paragraphs as noted:

Paragraph [0007]:

In accordance with one embodiment of the present invention, a cardiac harness is configured to fit generally around a patient's heart and to resist expansion of the heart by applying a compressive force thereto. At least a section of said harness exerts a circumferential load, normalized with respect to a longitudinal direction and expressed in

pounds per inch, as a function of circumferential expansion of said section of harness, expressed as a percent of expansion above a zero load condition. The harness has an operating range of expansion having a minimum value of at least 20 percent. A change of 20 percent in said circumferential expansion within said operating range yields a change in circumferential load of no more than about ~~0.066 lb/in~~ <u>0.116 N/cm (0.066 lbF/in)</u>.

Paragraph [0010]:

In accordance with another embodiment, the present invention provides a cardiac harness configured to fit generally around a patient's heart and to resist expansion of the heart by applying a compressive force thereto. At least a section of said harness exerts a circumferential load, normalized with respect to a longitudinal direction and expressed in pounds per inch, as a function of circumferential expansion of said section of harness, expressed as a percent of expansion above a zero load condition. The variation of load as a function of expansion between 20 percent expansion and 30 percent expansion is generally in the form of y=ax+b where "a" and "b" are determined by linear regression. The linear regression of said variation of load as a function of expansion yields a coefficient of determination of at least about 0.8. The value of "a" is no greater than about ~~0.0033~~ <u>0.0058 N/cm per percent expansion (0.0033 lbF/in per percent expansion)</u>.

Paragraph [0011]:

In another embodiment, the value of "a" is no greater than about ~~0.002~~ <u>0.0035 N/cm per percent expansion (0.002 lbF/in per percent expansion)</u>.

Paragraph [0025]:

Figure 13 shows a curve representing test data for ~~one embodiment of~~ a cardiac harness <u>constructed of a knit material</u>.

Paragraph [0083]:

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The above-described test procedure allows measurement of the elasticity/deformation behavior of various embodiments of cardiac harnesses so that such embodiments can be compared. For consistency, testing preferably is performed at room temperature, preferably about 37° C (98.6°F). As discussed above, the load is applied along the length L of the test portion 110, which length L is taken in a direction along the circumference of the corresponding harness. Thus, the applied load represents and corresponds to a circumferential load of the harness. The percent tensile strain is also taken along the length L. As such, the percent tensile strain represents and corresponds to a percent of circumferential expansion of the harness above a zero load condition.

Paragraph [0086]:

With reference also to Figure 15, plotted test data is presented for a test portion of a cardiac harness. The cardiac harness exemplified by the test data of Figure 15 comprises strands of spring elements preferably formed of drawn Nitinol wire having a diameter of about ~~0.008 in~~ 0.020 cm (0.008 in). The spring elements resemble the spring element 34 shown in Figure 14, and have a width w of about ~~0.165 in.~~ 0.419 cm (0.165 in), a height h of about ~~0.163 in.~~ 0.414 cm (0.163 in), and a diameter φ of about ~~0.126 in~~ 0.320 cm (0.126 in). After the wire is formed into strands of spring elements, it is heat treated at about 485° C (905° F) for about 30 minutes. Silicone tubing having an inner diameter of about ~~0.010 in.~~ 0.025 cm (0.010 in) and an outer diameter of about ~~0.025 in.~~ 0.064 cm (0.025 in) is disposed over the strand.

Paragraph [0088]:

With continued reference to Figure 15, a linear regression of the test data was performed in order to derive a function describing the behavior of the cardiac harness in the form y = ax + b. The linear regression was performed using Microsoft™ Excel™ software, and yielded the function ~~y = 0.001 x + 0.005~~ y = 0.0017x + 0.009 N/cm (y = 0.001x + 0.005 lbF/in). The linear regression function has a coefficient of determination R^2 of about 0.9969. It is understood that, in linear regression, the coefficient of

determination R^2 represents how well the linear regression function represents the collection of data. In the illustrated embodiment the R^2 value is very close to 1, and thus indicates that the linear regression line closely represents the data.

Paragraph [0089]:

With reference next to Figure 16, plotted test data is presented for a test portion of another embodiment of a cardiac harness. The cardiac harness exemplified by the test data of Figure 16 comprises strands of spring elements preferably formed of drawn Nitinol wire having a diameter of about ~~0.012 in~~ 0.031 cm (0.012 in). The spring elements resemble the spring element 34 shown in Figure 14, and have a width w of about ~~0.300 in.~~ 0.762 cm (0.300 in), a height h of about ~~0.275 in.~~ 0.699 cm (0.275 in), and a diameter φ of about ~~0.250 in~~ 0.635 cm (0.250 in). After the wire is formed into strands of spring elements, it is heat treated at about 485° C (905° F) for about 30 minutes. Silicone tubing having an inner diameter of about ~~0.014 in.~~ 0.036 cm (0.014 in) and an outer diameter of about ~~0.029 in.~~ 0.074 cm (0.029 in) is disposed over the strand.

Paragraph [0091]:

With continued reference to Figure 16, a linear regression of the test data was performed in order to derive a function describing the behavior of the cardiac harness in the form y = ax + b. The linear regression was performed using Microsoft™ Excel™ software, and yielded the function ~~y = 0.0009x + 0.0083~~ y = 0.0016x + 0.015 N/cm (y = 0.0009x + 0.0083 lbF/in). The linear regression function has a coefficient of determination R^2 of about 0.9864.

Paragraph [0092]:

With reference next to Figure 17, plotted test data is presented for a test portion of yet another embodiment of a cardiac harness. The cardiac harness exemplified by the test data of Figure 17 comprises strands of spring elements preferably formed of drawn Nitinol wire having a diameter of about ~~0.012 in~~ 0.031 cm (0.012 in). The spring

elements resemble the spring element 34 shown in Figure 14, and have a width w of about ~~0.300 in.~~ 0.762 cm (0.0300 in), a height h of about ~~0.275 in.~~ 0.699 cm (0.275 in), and a diameter φ of about ~~0.250 in~~ 0.635 cm (0.250 in). After the wire is formed into strands of spring elements, it is heat treated at about 485° C (905° F) for about 30 minutes. Silicone tubing having an inner diameter of about ~~0.014 in~~ 0.036 cm (0.014 in). and an outer diameter of about ~~0.029 in.~~ 0.074 cm (0.029 in) is disposed over the strand. As can be seen, the cardiac harness represented in Figure 17 is structurally very similar to the cardiac harness represented in Figure 16. In fact, the most significant difference between the harnesses is found in the arrangement of connectors between adjacent strands. As discussed above, due to the differences in connector placement, the longitudinal compliances of these embodiments are somewhat different. However, as set out below, the circumferential compliance of these embodiments is quite similar.

[00094] With continued reference to Figure 17, a linear regression of the test data was performed in order to derive a function describing the behavior of the cardiac harness in the form y = ax + b. The linear regression was performed using Microsoft™ Excel™ software, and yielded the function ~~y = 0.0009x + 0.0073~~ y = 0.0016x + 0.0128 N/cm (y = 0.0009x + 0.0073 lbF/in). The linear regression function has a coefficient of determination R^2 of about 0.9933.

Paragraph [0095]:

With reference next to Figure 18, plotted test data is presented for a test portion of another embodiment of a cardiac harness. The cardiac harness exemplified by the test data of Figure 18 comprises strands of spring elements preferably formed of drawn Nitinol wire having a diameter of about ~~0.011 in~~ 0.028 cm (0.011 in). The spring elements resemble the spring element 34 shown in Figure 14, and have a width w of about ~~0.165 in.~~ 0.419 cm (0.165 in), a height h of about ~~0.163 in.~~ 0.414 cm (0.163 in), and a diameter φ of about ~~0.126 in~~ 0.320 cm (0.126 in). After the wire is formed into

strands of spring elements, it is heat treated at about 485° C (905° F) for about 30 minutes. Silicone tubing is disposed over the strand.

Paragraph [0097]:

With continued reference to Figure 18, a linear regression of the test data was performed in order to derive a function describing the behavior of the cardiac harness in the form y = ax + b. The linear regression was performed using Microsoft™ Excel™ software, and yielded the function ~~y = 0.0033x + 0.0238~~ y = 0.0058x + 0.0417 N/cm (y = 0.0033x + 0.0238 lbF/in). The linear regression function has a coefficient of determination R^2 of about 0.9749.

Paragraph [0098]:

With continued reference to Figure 18, it is observed that the slope of the curve represented by the data points becomes lesser as the percent strain increases. A linear regression of the test data was performed in order to derive a function describing the behavior of the cardiac harness in the form $y = ex^2 + ax + b$. The linear regression was performed using Microsoft™ Excel™ software, and yielded the function ~~$y = -0.00005x^2 + 0.0054x - 0.0129$~~ $y = -0.000035x^2 + 0.0095x - 0.0226$ N/cm ($y = -0.00002x^2 + 0.0054x - 0.0129$ lbF/in). This linear regression function has a coefficient of determination R^2 of about 0.9989.

Paragraph [0099]:

Yet another embodiment of a cardiac harness comprises strands of spring elements formed of drawn Nitinol wire having a diameter of about ~~0.016 in~~ 0.041 cm (0.016 in). The spring elements resemble the spring element shown in Figure 14, and have a width w of about ~~0.289 in.~~ 0.734 cm (0.289 in), a height h of about ~~0.275 in.~~ 0.699 cm (0.275 in), and a diameter φ of about ~~0.250 in~~ 0.635 cm (0.250 in). After the wire is formed into strands of spring elements, it is heat treated at about 515° C (959° F) for about 25 minutes. Silicone tubing is disposed over the strand.

Paragraph [0100]:

A test portion of the just-described cardiac harness was tested in a materials testing machine in accordance with the procedure discussed above. Test data, including load and percent tensile strain, was collected between a zero load, zero percent strain condition and about a 100% strain condition. A linear regression of the test data was performed in order to derive a function describing the behavior of the cardiac harness in the form y = ax + b. The linear regression was performed using Microsoft™ Excel™ software, and yielded the function ~~y = 0.003x + 0.0073~~ y = 0.005x + 0.0128 N/cm (y = 0.003x + 0.0073 lbF/in). The linear regression function has a coefficient of determination R^2 of about 0.9945.

Paragraph [0103]:

Further, it is to be understood that, by employing the compliance functions that are derived from the test data by linear regression, the compliance behavior of the associated harnesses can be predicted over any range of expansion or load. For example, with reference to the embodiment of Figure 18, it can be determined that a change of about 20 percent in circumferential expansion within an operating range of expansion having a minimum value of at least 20 percent yields a change in circumferential load of about ~~0.066 lb/in~~ 0.116 N/cm (0.066 lbF/in).

Paragraph [0104]:

With reference to the embodiment of Figure 15, it can be determined that a change of about 20 percent in circumferential expansion within an operating range of expansion between about 0 and 100 percent yields a change in circumferential load of about ~~0.02 lb/in~~ 0.035 N/cm (0.02 lbF/in).

Paragraph [0105]:

Experimental studies indicate that a cardiac harness having compliance properties as in the embodiment of Figure 15 provide a beneficial therapeutic effect to a diseased heart. Studies also indicate that a cardiac harness having compliance properties as in the embodiment of Figure 18 also provides a beneficial therapeutic effect. Preferably, however, a cardiac harness has compliance properties at or more compliant than the embodiment of Figure 18. Thus, preferably a change of about 20 percent in circumferential expansion yields a circumferential load no greater than about ~~0.066 lb/in~~ 0.116 N/cm (0.066 lbF/in).

Paragraph [0106]:

As demonstrated by the several embodiments tested and discussed above, significant changes to the calculated compliance functions can be achieved by varying structural properties such as wire diameter, heat treatment, and dimensions of spring elements. It is anticipated that other cardiac harness embodiments can be constructed wherein a change of about 20 percent in circumferential expansion yields a change in circumferential load of about ~~0.066 lb/in., 0.02 lb/in., 0.018 lb/in.~~ 0.116 N/cm (0.066 lbF/in), 0.035 N/cm (0.022 lbF/in), 0.032 N/cm (0.018 lbF/in), or any range between or below these values.

Paragraph [0110]:

In the embodiments discussed above, the compliance function has been defined by linear regression of test data taken over a percent expansion between about 0-100%. It is to be understood that such an analysis may also be helpful if taken over a more limited range of percent expansion. For example, the operating range of the harness may, in some embodiments, be limited to such a range of expansion. In accordance with one embodiment, the variation of load as a function of expansion between about 20 - 30 percent expansion is represent by the compliance function y=ax+b in which "a" and "b"

are determined by linear regression, and wherein the value of "a" is no greater than about ~~0.0033~~ 0.0058 N/cm per percent expansion (0.0033 lbF/in per percent expansion).